

97S-0163

KYOLIC
Aged Garlic Extract™

Wakunaga of America Co., Ltd.
A Subsidiary of Wakunaga Pharmaceutical Co., Ltd.

VIA FEDERAL EXPRESS

June 27, 1997

Robert J. Moore, Ph.D.
Senior Regulatory Scientist
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
202 C Street, S.W., Room 4129C
Washington, D.C. 20204

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Dear Dr. Moore:

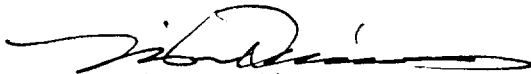
This responds to your letter of June 18, 1997, concerning our company's June 6, 1997 response to Dr. James Tanner's May 22, 1997 letter commenting on our company's notification of the statement of nutritional support for Probiata®.

Although we continue to disagree with your conclusion that the statement represents the product for use for "a drug-induced disease," and we believe that the original statement is appropriately a claim to affect the structure or function in humans, in order to resolve this matter amicably, we will revise the label for the product to delete the phrase you questioned. The revised statement of nutritional support will state:

Replenishes healthy intestinal flora, thereby promoting regular intestinal function. May be especially useful when taking antibiotics.

Please consider this letter as the notification required by section 403 (r) (6) of the Federal Food, Drug, and Cosmetic Act for this new statement of nutritional support for Probiata.

Sincerely,



Mitsuru Takiura
President

MT: dsh

cc: James T. Tanner, Ph.D., Acting Director

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